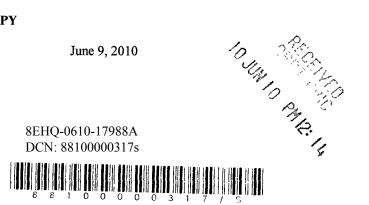
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Via Federal Express

Document Processing Center (Mail Code 7407M) Room 6428 Attention: 8(e) Coordinator Office of Pollution Prevention and Toxics U.S. Environmental Protection Agency, ICC Building 1201 Constitution Ave., NW Washington, DC 20004

8EHQ-0610-17988A DCN: 88100000317s



8EHG-10-17988

Dear 8(e) Coordinator:

Mixture containing 2-(2-Amino-ethoxy) ethanol (CAS#929-06-6) []; 1-Methyl-2-Pyrrolidone (CAS#872-50-]; Diethylene glycol (CAS#111-46-6) []; and Water (CAS#7732-18-5) [4) [

This letter is to inform you of the results of several studies with the above referenced test mixture.

Acute Dermal Toxicity:

In this acute dermal toxicity study, the dorsal area of skin of twelve young adult New Zealand White rabbits was clipped free of hair. A portion of the exposed skin was abraded and the balance left intact. Six rabbits were designated as test animals and six as controls. The test mixture was applied to the rabbits' skin at a dose of 2000 mg/kg body weight. The control animals were treated with wrappings moistened with distilled water. After 24 hours, the wrappings were removed, volume of unabsorbed material (if any) was measured, and skin reactions noted. The animals were wiped and cleaned and observed for gross symptoms of poisoning. observed for 14 days following application and were necropsied to detect grossly observable evidence of organ or tissue damage at the end of the 15-day test period.

All test animals exhibited skin discoloration at 24 hours and necrosis extending over large surface areas from day 4 through study termination (day 14). Under the conditions of this study, the dermal LD50 of the test mixture was greater than 2000 mg/kg in rabbits.

Dermal Irritation:

The test mixture was applied as a single 0.5-mL dermal dose to the shaved intact skin of 6 New Zealand White rabbits. The application area was covered with gauze squares which were securely taped and wrapped. At the end of a one-hour exposure period, the bandages were removed and the test mixture was washed from the skin. Test sites were evaluated and scored by the method of Draize for signs of dermal irritation at 4 and 48 hours after exposure.

At the 4-hour evaluation, two animals exhibited irreversible damage (i.e., necrosis or ulceration). remaining four animals had unusually discolored tissue (greenish-gray) which made evaluation uncertain. Severe edema was observed in four animals at 4 hours. Irreversible damage (i.e., necrosis or ulceration) as well as eschar formation was observed on the test site of all six rabbits at 48 hours. Severe erythema was noted in four animals at 48 hours.

Dermal Irritation:

The test mixture was applied as a single 0.5-mL dermal dose to the shaved intact skin of 6 New Zealand White rabbits. The test mixture was applied to an approximately 1 inch square area of skin. The application area was covered with a gauze patch which was held in place with tape and covered with porous tape for a semi-occlusive dressing. The rabbits were exposed to the test mixture for 4 hours after which the test mixture was removed. Test

Company Sanitized

sites were evaluated and scored by the method of Draize for signs of dermal irritation within approximately 30-60 minutes, 24, 48, and 72 hours, and on days 4 through 14.

Severe erythema was observed at the test site of all rabbits at the 30 to 60 minute observation and persisted in the rabbits through study termination (day 14). Severe edema was observed at the test site of all rabbits at the 30 to 60 minute and 24 hour observations. The severity of edema decreased and cleared by day 6. Necrosis, eschar, test mixture brownish/black in color, fissuring, and thickening were observed on the test site of all rabbits and persisted through study termination.

Eye Irritation:

The test mixture was applied undiluted at a dose of 0.1 mL to the right eye of two groups of three New Zealand White rabbits. The eyes remained unwashed. The rabbits were scored for irritation according to Draize at 1, 24, 48, and 72 hours and 4, 7, 10, 14, and 21 days following test mixture administration.

Severe corneal opacity (score of 4) and severe conjunctival redness (score of 3) were observed in the treated eye of all six rabbits, and severe conjunctival chemosis (score of 4) was observed in the treated eye of five rabbits. All six rabbits exhibited conjunctival petechial hemorrhage, conjunctival blanching, and conjunctival tissue black in color in the treated eye. Evaluation of the iris could not be conducted due to severe corneal opacity in one rabbit from 48 hours through day 4, and in two rabbits on days 7 through 21. At study termination (day 21), severe corneal opacity, mild to severe conjunctival redness, slight to severe conjunctival chemosis, corneal vascularization, and slight folding of the edge of the eyelid were still present in the treated eye of all six rabbits. Other ocular findings still present in the treated eye of 1-3 rabbits at 21 days included corneal epithelial sloughing, conjunctival blanching, a film of apparent conjunctival tissue or tissue mass covering the corneal surface, hair loss around the eyelid, and/or purulent discharge.

Acute Inhalation Toxicity:

The test mixture was aerosolized and the resulting test atmosphere (a mixture of vapor and droplets) was administered for four hours by whole-body inhalation exposure to a group of five male and five female Sprague-Dawley CD® rats at a concentration of 2.65 mg/l. A second group of five male and five female rats served as a control and received clean air only in a similar system for 4 hours.

None of the animals died during the study. The inhalation LC_{50} for male and female rats was greater than 2.65 mg/l. No clinical signs were observed in control animals. Piloerection, partially closed eyes, and hunched posture were observed in all test animals during the exposure period. On the day of exposure after the exposure period ended and on the day after exposure, three animals were sensitive to touch.

Skin Sensitization:

In the rangefinding phase of this skin sensitization study (Buehler method), Hartley guinea pigs were treated topically with various concentrations of test mixture, ranging from 1.3% to 100% (undiluted), to determine the irritation potential of the test mixture. Four of the four animals treated with a concentration of 100% exhibited severe erythema, eschar, necrosis, and edema at 24 and 48 hours. Three of the four animals treated with a concentration of 50% exhibited severe erythema and edema (severity not known) at 24 and 48 hours. One of these animals also exhibited eschar and necrosis at 24 and 48 hours. No severe irritation or necrosis was observed during the induction phase (8.0%) or the challenge phase (1.3%) of the study.

Under the conditions of this study, the test mixture demonstrated no potential to produce dermal sensitization when administered by the modified Buehler method to Hartley guinea pigs.

Sincerely,